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Japan

Food and Agricultural Import Regulations and Standards

Public Comment Period on Changes to Cadusafos MRL and Approval of 2 New Food Additives 2007

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Report Highlights:

On March 2 the Japanese Government announced proposed changes to the MRLs for Cudasofos and the planned approval of two new food additives, Isobutyraldehyde and 2-Methylbutanol. The comment period will close on March 16.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

Summary:

The Japanese Ministry of Health Labour and Welfare (MHLW) announced on March 2 proposed changes to the MRLs for the pesticide, Cadusafos and the proposed approval of two new food additives, Isobutyraldehyde and 2-Methylbutanol. The period for sending comments on these changes ends March 16. If you have comments it is best to send directly to MHLW as soon as possible, however MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date, and this will constitute the final decision.

If you have comments, please send them directly to the Japanese Government at:

Mailing Address:

Standards and Evaluation Division, Department of Food Safety,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916
Tel: 03-5253-1111
Fax: 03-3501-4868

E-mails for comments on MRLs:

Mr. N. KAWAMURA (kawamura-narihiko@mhlw.go.jp)
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Mr. M. DABA (daba-masaki@mhlw.go.jp)
Mr. D. TAKEUCHI (takeuchi-daisuke@mhlw.go.jp)
Tel. ex. 4273, 4281, 2486, 2487

E-mails for comments on Food Additives:

Mr. E. UCHIYAMA (uchiyama-eiji@mhlw.go.jp)
Mr. K. URA (ura-katsuaki@mhlw.go.jp)
Tel. ex. 2453

Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Details of Proposed Changes:**1) Establishment of Maximum Residue Limits for the Pesticides Cadusafos in Food****Purpose**

This activity is to develop specifications and standards for foods. Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare may establish residue standards (maximum residue limits: MRLs) for agricultural chemicals (pesticides, feed additives, and veterinary drugs) that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed unless such food complies with the established standards.

On November 29, 2005 the Ministry of Health, Labour and Welfare issued

notifications regarding the positive list system for agricultural chemicals in food (Notification Nos. 497, 498, and 499), which became effective on May 29, 2006. Basically, chemicals remaining in foods distributed in the Japanese marketplace must meet the residue standards.

Outline of the Activity

Cadusafos (Insecticide): This chemical is already approved in Japan. MAFF will expand the scope of target crops for which the use of the chemical is permitted. In response to MAFF's action, the MHLW will additionally establish MRLs for some crops and revise some of the MRLs which are specified in the Specifications and Standards for Food, Food Additives, Etc (see Attachment 1).

Attachment 1

Cadusafos(Insecticide)

Commodity	MRL (draft) ppm	Current MRL ppm
Soybeans, dry	0.01	
Potato	0.02	0.02
Taro	0.03	0.03
Sweet potato	0.02	0.02
Sugarcane	0.01	0.01
Japanese radish, roots (including radish)	0.05	0.05
Japanese radish, leaves (including radish)	0.05	0.05
Cabbage	0.01	0.01
Lettuce (including ice lettuce and leaf lettuce)	0.02	0.02
Welsh (including leek)	0.01	
Garlic	0.02	0.02
Tomato	0.01	0.01
Egg plant	0.02	0.02
Cucumber (including gherkin)	0.05	0.05
Pumpkin (including squash)		0.05
Water melon	0.01	0.01
Melons	0.02	0.02
Spinach	0.1	0.1
Ginger	0.1	0.1
Green soybeans	0.01	
Unshu orange, pulp	0.01	0.01
Citrus natsudaidai, whole	0.01	0.01
Lemon	0.01	0.01
Orange (including navel orange)	0.01	0.01
Grapefruit	0.01	0.01
Lime	0.01	0.01
Other citrus fruits ¹	0.01	0.01
Strawberry	0.05	0.05
Banana	0.01	0.01
Other herbs ¹	0.5	

Note: For commodities for which revised MRLs are not given, the uniform limit (0.01 ppm) will be applied. Limits given in the column of "MRL (draft)" include those that remain the same as the current MRLs.

1. "Other citrus fruits" refers to all citrus fruits, except unshu orange (pulp), citrus natsudaidai

(pulp), citrus natsudaïdai (peels), citrus natsudaïdai (whole), lemon, orange (including navel oranges), grapefruit, limes and spices.

2. "Other herbs" refers to all herbs, except watercress, nira, parsley stems and leaves, celery stems and leaves.

2) Designation of Food Additives (Isobutyraldehyde, 2-Methylbutanol)

Purpose

This activity is to newly designate two substances (Isobutyraldehyde, 2-Methylbutanol) as authorized food additives.

Under Article 10 of the Food Sanitation Law, food additives may be used or marketed only when they are designated by the Minister of Health, Labour and Welfare. Where use standards or specifications are established for additives under Article 11 of the law, those additives may be marketed only when they meet the established standards or specifications. In response to a request by the Minister for opinion, the Subcommittee on Food Additives under the Food Sanitation Committee under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the designation of these substances as food additives. The report from the subcommittee is outlined as below.

Outline

The Minister should designate Isobutyraldehyde and 2-Methylbutanol based on Article 10 of the Food Sanitation Law as food additives not injurious to human health. Under Article 11 of the law, compositional specifications and use standards for these substances should be established. (See Attachments 2 and 3).

Additional Information

Progress in the designation procedure of food additives that have been proven safe by JECFA (Joint FAO/WHO Expert Committee on Food Additives) and that are widely used in countries other than Japan (Attachment 4)

(Attachment 2)

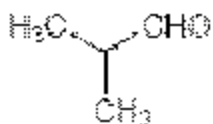
Isobutyraldehyde

Standard for use: It must not be used for purposes other than flavoring.

Compositional specifications

Substance name: Isobutyraldehyde (Isobutanol)

Structural formula:



Molecular formula: C₄H₈O

Molecular Weight: 72.11

Chemical name, CAS number: 2-Methylpropanal [78-84-2]

Content: Isobutyraldehyde contains not less than 98.0% of isobutyraldehyde (C₄H₈O).

Description: Isobutyraldehyde is a colorless and clear liquid having a characteristic odor.

Identification: Determine the infrared absorption spectrum of Isobutyraldehyde, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wave numbers.

Purity (1) Refractive index n_D^{20} : 1.369–1.379.

(2) Specific gravity d_{4}^{25} : 0.783–0.788

(3) Acid value Not more than 5.0 (Flavoring Substance Tests).

Assay: Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2).

(Attachment 3)

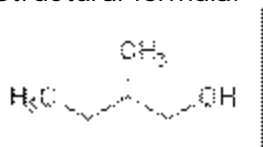
2-Methylbutanol

Standard for use: It must not be used for purposes other than flavoring.

Compositional specifications

Substance name: 2-Methylbutanol

Structural formula:



Molecular formula: C₅H₁₂O

Molecular Weight: 88.15

Chemical name, CAS number: 2-Methylbutan-1-ol [137-32-6]

Content: 2-Methylbutanol contains not less than 99.0% of 2-Methylbutanol (C₅H₁₂O).

Description: 2-Methylbutanol is a colorless and clear liquid, having a characteristic odor.

Identification: Determine the infrared absorption spectrum of 2-Methylbutanol, as

directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wave numbers.

Purity (1) Refractive index

n_D^{20} : 1.408-1.412

(2) Specific gravity

d_4^{20} : 0.815-0.820

(3) Acid value: Not more than 1.0 (Flavoring Substance Tests).

Assay: Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2).